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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,989	02/08/2002	Randy Dinkins	028750-219	9928

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/067,989	Applicant(s) DINKINS ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,15-27,32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,10-14 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-33 are pending.
2. This application contains claims 8-9, 15-27 and 32-33 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims/deletion of nonelected subjected matter from the examined claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The objection to claims 7, 13 and 31 because of informalities is withdrawn in light of Applicant's amendments to the claims.
5. The rejection of claims 28-31 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn in light of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

6. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector encoding the *Arabidopsis* MinD protein, plants and cells transformed with it and a method of using it to produce a plant with one or few chloroplasts, does not reasonably provide enablement for vectors comprising a gene encoding a protein with the same functional activity as the *Arabidopsis* MinD protein or encoding a derivative of the *Arabidopsis* MinD protein, plants and cells transformed with them and a method of using them to produce a plant with one or few chloroplasts. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 16 June 2003. Applicant's arguments filed 16 September 2003 have been fully considered but they are not persuasive.

Applicant urges that there is enablement for vectors encoding a protein with the same functional activity as the Arabidopsis MinD protein or encoding a derivative of the Arabidopsis MinD protein, plants and cells transformed therewith and a method of using them to produce a plant with one or few chloroplasts (response pg 11).

This is not found persuasive because the instant specification fails to teach genes that encode proteins with the same functional activity as the Arabidopsis MinD gene and fails to teach derivatives of the Arabidopsis MinD gene.

Applicant urges that the MinD databases at the NCBI website provide over 300 sequences with high homology to the MinD gene; MinD has a cluster of orthologous group of proteins and is thus well-recognized in prokaryotes. Applicant urges that one of skill in the art would know that MinD is similar across species and has the signature of a septum-formation inhibitor-inactivating ATPase. Applicant urges that one of skill in the art can use the databases to prepare primers and identify appropriate derivatives of the MinD gene (response pg 11-12).

This is not found persuasive because the MinD database (COG2894.1, MinD) was created on 7 October 2002, which is after the 8 February 2002 filing date of the instant application. See *In re Glass*, 181 USPQ 31, 34 (CCPA 1974), which teaches that references

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published after the filing date of an application may not be relied upon for the enablement of the specification.

Applicant urges that the specification provides sufficient guidance as to which amino acids of SEQ ID NO:1 can be altered and which cannot to maintain MinD activity; based on the homology provided by the NCBI database above, one of skill in the art would have sufficient guidance to know which amino acids to alter (response pg 12).

This is not found persuasive because the MinD database (COG2894.1, MinD) was created on 7 October 2002, which is after the 8 February 2002 filing date of the instant application.

Furthermore, Hill et al, cited in the prior Office action, teach that three presumably catalytic histidines that are maintained in the same position ADP-glucose pyrophosphorylase across 11 bacterial and plant species (abstract and pg 573, right column, paragraph 3); one would expect that an amino that is so strongly conserved would tolerate either no substitutions or only conservative substations with other basic amino acids. The substitution of one of those histidines with the conservative amino acid arginine drastically reduced enzyme activity; however, substitution with the nonconservative amino acid glutamine, had little effect on enzyme activity (see Table 1). Lazar et al, cited in the prior Office action, showed that the “conservative” substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while “nonconservative” substitutions with alanine or asparagine had no effect (abstract). Thus, amino acid substitution is unpredictable.

7. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 16 June 2003. Applicant's arguments filed 16 September 2003 have been fully considered but they are not persuasive.

Applicant urges that the appropriate vectors encoding a derivative of the *Arabidopsis* MinD protein would be easily determined by the skilled artisan through what was known in the art at the time of filing, for example using the NCBI database (response pg 13).

This is not found persuasive because the MinD database (COG2894.1, MinD) was created on 7 October 2002, which is after the 8 February 2002 filing date of the instant application. The specification does not describe vector encoding a derivative of the *Arabidopsis* MinD protein, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

8. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 16 June 2003, due to amendment of the claims. Applicant's arguments filed 16 September 2003 have been fully considered but they are not persuasive.

Claims 1, 5-7, 10-13 and 28-31 are indefinite in their recitation of "exogenous". It is not clear to what the gene is exogenous - the vector? *Arabidopsis*? a randomly chosen plant?

Applicant urges that this term is well-known to the skilled artisan as meaning developed outside the organism in question, citing Stedman's Medical Dictionary. Applicant thus urges that the *Arabidopsis* gene is exogenous in tobacco but not in *Arabidopsis* (response pg 13-14).

This is not found persuasive. With respect to the vector of claim 1 it is not clear what organism the gene would be exogenous to. The vector that can be used to transform tobacco can also be used to transform *Arabidopsis* - does this mean the vector cannot have a MinD gene from either *Arabidopsis* or tobacco? Does it mean it can't have any plant mind gene? Furthermore, the MinD gene that is transformed into the plant would be exogenous because it would "originate" from outside the plant, simply because it would be an transformation vector and would have been introduced from "outside" the plant. For the claimed plants and methods, the plants into which the exogenous gene is transformed would have an endogenous MinD gene; another copy of the gene would be exogenous because it would come from outside the plant.

Claims 1, 10 and 28 are indefinite in their recitation of "a protein with the same functional activity as a protein encoded by the *Arabidopsis thaliana* ... *MinD* gene". It is unclear which protein encoded by the *MinD* gene is being referred to. Additionally, it is not clear what the exact function of the *Arabidopsis* MinD protein - what proteins does it interact with, what is its exact enzymatic activity?

Applicant urges that one of skill in the art would know what proteins and sequences are appropriate in the context of the present invention from reviewing the sequence homologies found at the NCBI database (response pg 14).

This is not found persuasive because the MinD database (COG2894.1, MinD) was created on 7 October 2002, which is after the 8 February 2002 filing date of the instant application. Furthermore, the specification needs to teach these things.

Claims 7, 13 and 31 are indefinite in their recitation of “gene is derived from *Arabidopsis thaliana* MinD gene”. It is unclear how the gene differs from the *Arabidopsis* gene.

Applicant urges that what is meant by the phrase would be well-known to the skilled artisan and the phrase is defined on pg 7, lines 19-25, of the specification (response pg 15).

This is not found persuasive. As stated in the prior Office action, the definition on pg 7, lines 19-25, of the specification because is confusing and meaningless because it uses the words it is defining in the definition (“‘derived from’ a known gene or protein means that the gene or protein is the native known gene or protein, or ... is derived therefrom”). Applicant fails to point out what one of skill in the art would know is meant by the phrase. It remains unclear how the gene differs from the *Arabidopsis* gene.

The following rejections are new, due to amendment of the claims:

Claims 5, 11 and 29 are indefinite in their recitation of “derived from a gene of *Arabidopsis thaliana*”. It is unclear how the gene differs from the *Arabidopsis* gene.

Claim Rejections - 35 USC § 102

9. Claims 1-7, 10-13 and 28-31 remain rejected under 35 U.S.C. 102(a) as being anticipated by Colletti et al (2000, Curr. Biol. 10:507-516). The rejection is repeated for the reasons of record as set forth in the Office action mailed 16 June 2003. Applicant’s arguments filed 16 September 2003 have been fully considered but they are not persuasive.

Applicant urges that Colletti et al do not teach all elements of the claimed invention, which is the use of pMidD in a heterologous system and a different species, tobacco (response pg 16).

This is not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (*i.e.*, use of pMidD in tobacco) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant urges that the instant invention provides a system to increase the efficiency of chloroplast transformation because having only one or few large chloroplasts in a cell increases the target area for particle bombardment, and eliminating the need for multiple transfers in tissue culture to increase the percentage of transgenic homoplastic cells in the regenerating cells. Applicant urges that once the chloroplast is transformed, the MinD transgene can be eliminated by outcrossing (response pg 16-17).

This is not found persuasive because, again, Applicant is arguing limitations not in the claims. Furthermore, the vectors, plants and methods of Colletti et al would inherently increase the target area for particle bombardment, and eliminate the need for multiple transfers in tissue culture to increase the percentage of transgenic homoplastic cells in the regenerating cells because they produce plants with one or few large chloroplasts in the cell.

Applicant urges that Colletti et al do not teach all elements of the claimed invention as it fails to recite the system of increased efficiency (response pg 17).

This is not found persuasive because, as stated above, Colletti et al disclose vectors, plants and methods that inherently disclose a system of increased efficiency.

Lastly, it is noted that the vector of Colletti et al and the vector taught on pg 20, lines 7-26 of the instant specification both comprise the Arabidopsis MinD coding sequence operably linked to the 35S promoter.

10. Claims 1-7, 10-13 and 28-31 remain rejected under 35 U.S.C. 102(a) as being anticipated by Kanamaru et al (2000, Plant Cell Physiol. 41:1119-1128 and GenBank Accession No. AB030278, December 2000). The rejection is repeated for the reasons of record as set forth in the Office action mailed 16 June 2003. Applicant's arguments filed 16 September 2003 have been fully considered but they are not persuasive.

Applicant urges that Kanamaru et al do not teach all elements of the claimed invention as it fails to recite the system of increased efficiency, rather than just providing larger chloroplasts (response pg 17-).

This is not found persuasive because the vectors, plants and methods of Kanamaru et al would inherently increase the target area for particle bombardment, and eliminate the need for multiple transfers in tissue culture to increase the percentage of transgenic homoplastic cells in the regenerating cells because they produce plants with one or few large chloroplasts in the cell.

Lastly, it is noted that the vector of Kanamaru et al and the vector taught on pg 20, lines 7-26 of the instant specification both comprise the Arabidopsis MinD coding sequence operably linked to the 35S promoter.

11. Claims 1-2 and 5-7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al (1996, J. Bacteriol. 178:5080-5085). The rejection is repeated for the reasons of record as set forth in the Office action mailed 16 June 2003. Applicant's arguments filed 16 September 2003 have been fully considered but they are not persuasive.

Applicant urges that the claimed invention is a system of increased efficiency, rather than just providing larger chloroplasts, and Huang et al do not disclose that, thus failing to recite every element of the claimed invention (response pg 17).

This is not found persuasive because the vectors of Huang et al inherently comprise a gene that if it were expressed in a plant cell would increase the target area for particle bombardment, and eliminate the need for multiple transfers in tissue culture to increase the percentage of transgenic homoplastic cells in the regenerating cells because they produce plants with one or few large chloroplasts in the cell.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
November 19, 2003



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